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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,247	10/23/2001	Daniel J. Cook	39726/29361	4051

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EXAMINER
PATEL, MITAL B

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,247	COOK, DANIEL J.	
	Examiner	Art Unit	
	Mital B. Patel	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 July 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/12/04 has been entered.

Response to Amendment/Arguments

2. Applicant's arguments, see Amendment, filed 4/19/04, with respect to the rejection(s)of claim(s) 1-9 under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of DiPietropolo (US 4751922) and DiPietropolo (US 4751922) in view of Stone et al (US 5527316).

3. The declaration under 37 CFR 1.132 filed 4/19/04 is sufficient to overcome the rejection of claims set forth in the final office action based upon 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 6, 8, 9, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by DiPietropolo (US 4,751,922).

6. **As to claim 1**, DiPietropolo teaches an endo-tracheal tube retainer (**it should be noted that because DiPietropolo teaches all the structure set forth in claim 1 below, it is inherently capable of retaining an endo-tracheal tube**) comprising a solid (**See Col. 4, lines 25-26 and lines 32-35, which disclose that the rod *may be* (emphasis) bored which the Examiner interprets to mean that DiPietropolo also teaches a solid rod; additionally, the Examiner contends that even if the rod is bored, it receives a guide-pin which would make the rod solid**) semi-rigid (**See Fig. 2 which shows the rod being flexible yet still able to maintain rigidity as depicted in Fig. 1; See also Col. 4, lines 23-24**) stylet rod **1** having proximal and distal ends, said stylet rod **1** having a base portion at the distal end of the rod integral with said distal end (**See Col. 4, lines 36-55**); and a connection adapter **3** tapered from a proximal end of said connection adapter **3** to a distal end (**See Fig. 1 attachment below**) of said connection adapter **3** for secure insertion within a range of endotracheal tubes, said adapter **3** being connected to said base portion of the distal end of said solid stylet rod **1** (**See Col. 4, lines 36-55**), wherein at least a portion of the connection adapter **3** has an outer diameter in the range of about 2.0 mm to about 14.0 mm (**See Col. 4, lines 28-29 which teaches a 13 mm adaptor which falls within the range recited**).

7. **As to claim 2**, DiPietropolo teaches an endo-tracheal tube retainer (**it should be noted that because DiPietropolo teaches all the structure set forth in claim 1 below, it is inherently capable of retaining an endo-tracheal tube**) wherein the endo-tracheal tube retainer is used to facilitate the removal of the laryngeal mask of the type having a flexible respiratory tube, and that is sufficiently small in diameter to pass through a flexible respiratory tube (**Please note that DiPietropolo teaches all of the structure recited in claim 1 and as such is inherently capable of performing the function set forth in claim 2**).

8. **As to claim 3**, DiPietropolo teaches an endo-tracheal tube retainer (**it should be noted that because DiPietropolo teaches all the structure set forth in claim 1 below, it is inherently capable of retaining an endo-tracheal tube**) wherein the stylet **1** is adapted for use independently of the endo-tracheal tube as an intubating stylet (**Please note that DiPietropolo teaches all of the structure recited in claim 1 and as such is inherently capable of performing the function set forth in claim 3**).

9. **As to claim 4**, DiPietropolo teaches an endo-tracheal tube retainer wherein the semi-rigid stylet **1** is of sufficient length (**Please note that Applicant has not clearly defined what this sufficient length constitutes, however, please see Col. 4, lines 27-31 which teaches a stylet length of 20 inches which is more than a sufficient length to perform the function set forth**) to extend from the laryngeal opening to a point external to a patient's oral cavity.

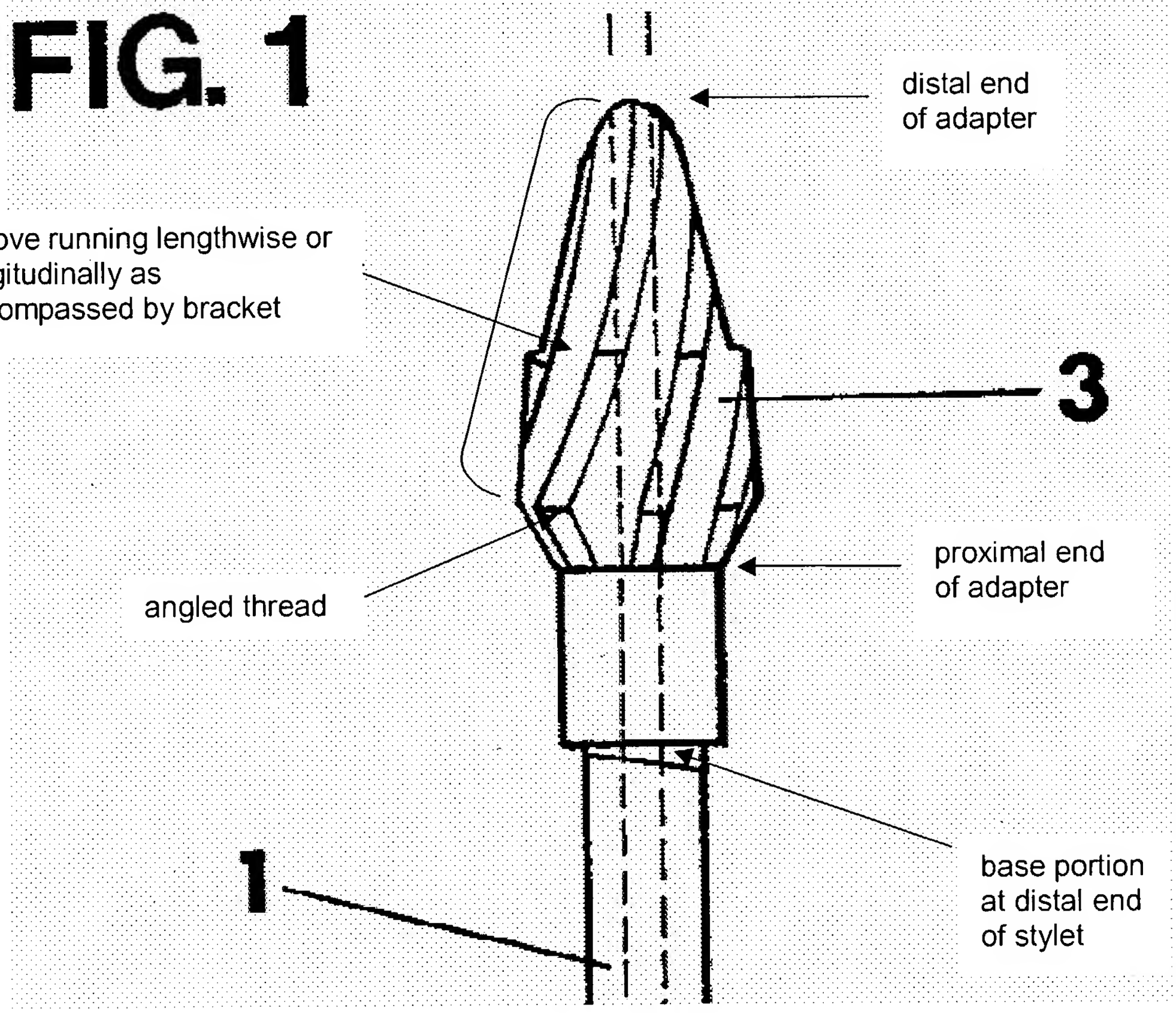
10. **As to claim 6**, DiPietropolo teaches an endo-tracheal tube retainer wherein an exterior surface of the connection adapter **3** comprises a plurality of longitudinal grooves

(Please see Fig. 1 attachment below; Also note that longitudinal is defined in Merriam-Webster's Collegiate Dictionary, 10th Ed. as placed or running lengthwise and the Examiner considers DiPietropolo to teach grooves running lengthwise on the adaptor from one end lengthwise to the other end; furthermore, Applicant recites longitudinal grooves on an exterior surface and does not recite longitudinal grooves running along the entire length of the exterior surface of the adaptor) permitting passage of air and fluids past the endo-tracheal tube retainer after insertion within an endo-tracheal tube; and a plurality of threads angled (**See Fig. 1 attachment below**) to facilitate insertion of said endo-tracheal tube retainer within an endo-tracheal tube, but hindering withdrawl of said endo-tracheal tube retainer from said endo-tracheal tube (**Please note that given the structure the device is inherently capable of performing the functions set forth**).

11. **As to claim 8**, DiPietropolo teaches an endo-tracheal tube retainer wherein the longitudinal grooves are equi-spaced around the connection adapter **3** exterior surface (**See Fig. 1 attachment below**).

12. **As to claim 9**, DiPietropolo teaches an endo-tracheal retainer wherein there are at least four longitudinal grooves (**See Fig. 1 attachment below; please note only 3 are shown, the remaining grooves being on the other side of the adapter**).

FIG. 1



13. **As to claim 17**, DiPietropolo teaches an endo-tracheal tube retainer (**it should be noted that because DiPietropolo teaches all the structure set forth in claim 17 below, it is inherently capable of retaining an endo-tracheal tube**) comprising a

solid (**See Col. 4, lines 25-26 and lines 32-35, which disclose that the rod *may be* (emphasis) bored which the Examiner interprets to mean that DiPietropolo also teaches a solid rod; additionally, the Examiner contends that even if the rod is bored, it receives a guide-pin which would make the rod solid**) semi-rigid (**See Fig. 2 which shows the rod being flexible yet still able to maintain rigidity as depicted in Fig. 1; See also Col. 4, lines 23-24**) stylet rod **1** having proximal and distal ends, said stylet rod having a base portion at the distal end of the rod integral with said distal end (**See Col. 4, lines 36-55**); and a connection adapter **3** tapered from a proximal end of said connection adapter **3** to a distal end (**See Fig. 1 attachment above**) of said connection adapter **3** for secure insertion within a range of endotracheal tubes, said adapter **3** being connected to said base portion of the distal end of said solid stylet rod **1** (**See Col. 4, lines 36-55**), wherein at least a portion of the connection adapter has an outer diameter in the range of about 2.0 mm to about 14.0 mm (**See Col. 4, lines 28-29 which teaches a 13 mm adaptor which falls within the range recited**), and wherein an exterior surface of the connection adapter **3** comprises a plurality of longitudinal grooves (**Please see Fig. 1 attachment above; Also note that longitudinal is defined in Merriam-Webster's Collegiate Dictionary, 10th Ed. as placed or running lengthwise and the Examiner considers DiPietropolo to teach grooves running lengthwise on the adaptor from one end lengthwise to the other end; furthermore, Applicant recites longitudinal grooves on an exterior surface and does not recite longitudinal grooves running along the entire length of the exterior surface of the adaptor**) permitting passage of air and fluids past the endo-tracheal tube retainer after

insertion within an endo-tracheal tube; and a plurality of threads angled (**See Fig. 1 attachment above**) to facilitate insertion of said endo-tracheal tube retainer within an endo-tracheal tube, but hindering withdrawl of said endo-tracheal tube retainer from said endo-tracheal tube (**Please note that given the structure the device is inherently capable of performing the functions set forth**).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over DiPietropolo (US 4,751,922) over Stone et al (US 5,5257,316).

16. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. **As to claim 7**, DiPietropolo teaches essentially all of the limitations except for wherein the connection adapter is composed of soft, semi-rigid material sufficiently flexible to permit the connection adapter to traverse through the endo-tracheal tube after

positioning within the oropharynx region. Stone et al also teaches a reamer with a connection adaptor/head which is composed of a soft, semi-rigid material sufficiently flexible (**See Col. 3, lines 39-40 of Stone et al, it should be noted that with respect to the descriptors "soft, semi-rigid", Applicant's connection adaptor is threaded and therefore, Examiner interprets soft, semi-rigid to mean that it is made of a material that would allow for the adaptor to flex and as such Stone et al teaches a soft, semi-rigid material**) so that the adaptor may be able to flex and curve relative to its axis in order to follow the shape of a particular anatomy of the patient. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the adaptor of DiPietropolo to be flexible as taught by Stone et al so that the adaptor may flex and curve relative to its axis in order to follow the natural curve of a particular anatomy of the patient (**Please note that both the DiPietropolo reference and Stone et al reference are analogous art since both are of the reamer art, thereby making the 103(a) rejection proper to arrive at the recited structural limitations; and therefore, having the structure results in an inherent capability to perform the intended use/function**).

Allowable Subject Matter

18. The indicated allowability of claims 10-16 is withdrawn in view of further consideration of Cook (US 6,422,239). Rejections based on double patenting follow.

Double Patenting

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

20. Claims 10-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-7 of U.S. Patent No. 6,422,239. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are more specific than the application claims and therefore, the patent claims anticipate the application claims. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993).

21. **Claim 10 of the application** recites " a method for removing an inflatable laryngeal mask from a patient without dislodging any inserted endotracheal tubes or related medical instruments into the patient's laryngeal opening by using a tube retaining device, the method comprising the steps of" (**See lines 1-6 of claim 1 of the patent**): "inserting the tube retaining device through an opening in the inflatable laryngeal mask exterior to the oral cavity (**See lines 1-3 of claim 2 of the patent**); securing the tube retaining device within a proximal end of the previously inserted endo-

tracheal tube within said inflatable laryngeal mask" (**See lines 9-10 of claim 1 of the patent**); "deflating said inflatable laryngeal mask" (**See line 11 of claim 1 of the patent**); "simultaneously withdrawing said deflated inflatable laryngeal mask from the patient's oral cavity and exerting a retaining force on the tube retaining device sufficient to prevent friction from dislodging said endo-tracheal tube (**See lines 12-16 of claim 1 of the patent**); and sliding the inflatable laryngeal mask off the proximal end of said retaining device" (**See lines 17-18 of claim 1 of the patent**). The difference between claim 10 of the application and claim 2 of the patent lies in the fact that the patent claim includes additional elements and is thus more specific. Thus the invention of claim 2 of the patent is in effect a "species" of the "generic" invention of claim 10 of the application; and therefore, the generic invention of claim 10 of the application is anticipated by the species and is not patentably distinct from claim 2 of the patent.

22. **Claim 11 of the application** recites " a method for removing an inflatable laryngeal mask from a patient without dislodging any inserted endo-tracheal tubes or related medical instruments into the patient's laryngeal opening by using a tube retaining device, the method comprising the steps of" (**See lines 1-6 of claims 1, 3 and 5 of the patent**): securing the tube retaining device within a proximal end of an endotracheal tube" (**See lines 9-10 of claims 1 and 3 of the patent, lines 8-10 of claim 5 of the patent**); "inserting the endotracheal tube through an opening in the inflatable laryngeal mask" (**See line 2-4 of claims 1, 3 and 5 of the patent**); "removing said inflatable laryngeal mask by withdrawing said inflatable laryngeal mask from the patient's oral cavity and exerting a retaining force on the tube retaining device sufficient

to prevent friction from dislodging said endo-tracheal tube (**See lines 12-18 of claim 1 of the patent, lines 12-17 of claim 3 of the patent, lines 11-15 of claim 5 of the patent**); and removing the inflatable laryngeal mask" (**See lines 12-18 of claim 1 of the patent, lines 12-17 of claim 3 of the patent, lines 11-15 of claim 5 of the patent; see also claim 6 of the patent**). The difference between claim 11 of the application and claims 3, 5, and 6 of the patent lies in the fact that the patented claims include additional elements; and thus, are more specific. Thus, the invention of claims 3, 5, and 6 of the patent is in effect a "species" of the "generic" invention of claim 11 of the application; and therefore, the generic invention of claim 11 of the application is anticipated by the species and is not patentably distinct from claims 3, 5, and 6 of the patent.

23. **Claim 12 of the application** recites "wherein removing the inflatable laryngeal mask comprises separating the tube retaining device from the endotracheal tube and sliding the inflatable laryngeal mask off an end of the tube retaining device" (**See lines 16-17 of claim 3 of the patent and claims 6 and 7 of the patent**).

24. **Claim 13 of the application** recites "wherein removing the inflatable laryngeal mask comprises separating the tube retaining device from the endotracheal tube and sliding the inflatable laryngeal mask off a proximal end of the tube retaining device" (**See lines 16-17 of claim 3 of the patent and claim 7 of the patent**).

25. **Claim 14 of the application** recites " a method for removing an laryngeal mask from a patient without dislodging any inserted endo-tracheal tubes or related medical instruments into the patient's laryngeal opening by using a tube retaining device, the method comprising the steps of" (**See lines 1-6 of claims 1, 3 and 5 of the patent**):

"inserting an endotracheal tube through an opening in the laryngeal mask" (**See lines 2-4 of claims 1, 3 and 5 of the patent**); "securing the tube retaining device within the endotracheal tube" (**See lines 9-10 of claims 1 and 3 of the patent, lines 8-10 of claim 5 of the patent**); "removing the laryngeal mask by withdrawing the laryngeal mask from the patient's oral cavity and exerting a retaining force on the tube retaining device sufficient to prevent dislodging the endo-tracheal tube (**See lines 12-16 of claim 1 of the patent, lines 12-17 of claim 3 of the patent, lines 11-15 of claim 5 of the patent**); and removing the laryngeal mask" (**See lines 12-16 of claim 1 of the patent, lines 12-17 of claim 3 of the patent, lines 11-15 of claim 5 of the patent; see also claim 6 of the patent**). The difference between claim 14 of the application and claims 1, 3, 5, and 6 of the patent lies in the fact that the patented claims include additional elements; and thus, are more specific. Thus, the invention of claims 1, 3, 5, and 6 of the patent is in effect a "species" of the "generic" invention of claim 14 of the application; and therefore, the generic invention of claim 14 of the application is anticipated by the species and is not patentably distinct from claims 1, 3, 5, and 6 of the patent.

26. **Claim 15 of the application** recites "wherein removing the laryngeal mask comprises separating the tube retaining device from the endotracheal tube and sliding the inflatable laryngeal mask off an end of the tube retaining device" (**See lines 17-18 of claim 1 of the patent, lines 16-17 of claim 3 of the patent and claims 6 and 7 of the patent**).

27. **Claim 16 of the application** recites "wherein removing the laryngeal mask comprises sliding the inflatable laryngeal mask off a proximal end of the tube retaining

device" (**See lines 17-18 of claim 1 of the patent, lines 16-17 of claim 3 of the patent and claim 7 of the patent**).

Conclusion

28. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5720749, 5562371, US 5562673, US 5326196, US 5222487, US 5037251, US 5033919, US 4661028, US Re. 31948, US 3945069, US 3606669, US 2787010, US 2335741, US 1345425, and US 678814.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (8:00 - 4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

8/7/04

Mital B. Patel
Examiner
Art Unit 3743